GENORAY

K091918

Exhibit 5 **510(k) Summary**

Fluoroscopic X-Ray System / Model: ZEN-2090 Pro

1. Submitter and US Official Correspondent

Submitter:	GENORAY Co., Ltd.
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Telephone No.:	+82-31-737-8020
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Official Correspondent (U.S):Shin Kuk Yoo, Consultant

Telephone No.:	714-313-7442
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Email:	skyone@LSKBioPartners.com

OCT - 7 2009

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name:	Fluoroscopic X-Ray System (Model: ZEN-2090 Pro)
Common/Usual Name:	Fluoroscopic X-Ray System
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Product Code:	JAA
Device Class:	Class II per regulation 21 CFR 892.1650

4. Equivalent Legally Marketed Device

<GE OEC Fluorostar>

Manufacturer:	GE OEC Medical Systems, Inc.
Device Name:	GE OEC Fluorostar
510(k) Number:	K043076 (Decision Date – Dec. 22, 2004)
Classification:	Image-Intensified Fluoroscopic X-Ray System: JAA, Class II per regulation 21 CFR 892.1650

<Philips BV Endura>

Manufacturer:	Philips Medical Systems North America Company
Device Name:	Philips BV Endura
510(k) Number:	K010435 (Decision Date – Mar. 12, 2001)
Classification:	Image-Intensified Fluoroscopic X-Ray System: JAA, Class II per regulation 21 CFR 892.1650

5. ~~Description of the Device~~

ZEN-2090 Pro is consisted of the X-ray tube, X-ray tube assembly, x-ray controller, XTV camera and some accessories.

The ZEN-2090 Pro is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Product / Items	ZEN-2090 Pro
Generator	High Frequency Inverter
X-ray tube	Stationary tube
Fluoroscopy	40~110 kV / 0.2~6mA Boost mode:10mA ABC control
Radiography	40 ~ 110 kV/20mA
TV Camera	CCD Type
Frame Memory	16 Frame
Image Intensifier	E5830SD-P4A of Toshiba
Panning motion	±12.5°
Parallel motion	N/A
Orbit. Rotation	120 Degrees
Horiz. Travel	200mm
Vert. Travel	400mm
Rotation	180 Degrees about
Panning motion	±12.5°
Parallel motion	N/A

6. Indications for use

ZEN-2090 Pro is a mobile digital C-arm designed to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, orthopedic, neurologic, stone localization, critical care and emergency room procedures

i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the operating room.

7. Safety and Effectiveness, comparison to Predicate

The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

GENORAY Co., Ltd.
% Mr. Shin Kuk Yoo
Consultant Manager
LSK BioPartners, Inc.
215 South State Street, Suite 100B
SALT LAKE CITY UT 84111

MAY 16 2012

Re: K091918
Trade/Device Name: Fluoroscopic X-Ray System (Models: ZEN-2090 Pro)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, and JAA
Dated: September 4, 2009
Received: October 1, 2009

Dear Mr. Yoo:

This letter corrects our substantially equivalent letter of October 7, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit 4 **Indications for Use**

510(k) number (if known): K091918

Device Name: Fluoroscopic X-Ray System (Models: ZEN-2090 Pro)

Indications for Use:

~~ZEN-2090 Pro is a mobile digital C-arm designed to provide fluoroscopic and radiographic~~ images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, orthopedic, neurologic, stone localization, critical care and emergency room procedures

i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the operating room.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091918